REMARKS:

This application is a continuation of Application Serial No. 09/865,915 (the "Parent Application"), filed May 25, 2001. Claims 11-16 and 21-22 of the Parent Application were rejected under 35 USC §§112 and 103(a). New claims 1-17 are pending in this application. They are believed to satisfy the requirements of §112 and, as discussed below, are believed patentable over the art of record in the Parent Application. Allowance of these claims is therefore respectfully requested.

Intravenous catheters and other catheter introducers are typically mounted over an introducer needle having a sharp tip. The catheter and introducer needle assembly is inserted at a shallow angle through the patient's skin into a blood vessel. Once the catheter is in place, the needle is withdrawn. Some of these assemblies include a side port while others include a port at the rear end. Due to the various structures of such catheter and introducer assemblies, as well as regional preferences, a clinician will likely develop a preference for a particular insertion technique. However, this technique may not be useable with a given catheter and introducer assembly purchased by a hospital. Consequently, the clinician must modify the technique for a given device. This may be particularly undesirable because of the technique sensitive nature of catheter insertion procedures. The instant disclosure addresses these challenges by providing structures incorporated into devices that permit the use of either technique with a single device, without interfering with the sound operation of the device.

Claims 11-16 and 21-22 of the Parent Application were rejected under 35 USC §103(a) in view of various combinations of Kvalo (U.S. Patent 4863432), Purdy (U.S. Patent 5215528) and Edwards (US Patent 5370624). The claims of the instant invention are believed patentable over these references. Further, there is no teaching or suggestion in the prior art to combine the references to achieve the claimed invention.

Looking specifically at claim 1, it is directed to a multi-grip catheter and needle assembly including a needle shield. Finger grips are provided at the sides of a needle hub and a thumb pad is provided at the proximal end of the thumb pad. This thumb pad has a convex shape while the finger grips have a concave shape, encouraging secure gripping by the clinician. A push tab extends radially from the needle shield, with a convex distal face and a concave proximal face. At least one wing is attached to a catheter adapter. The distal edge of the wing is convex and positioned distal to the push tab.

Kvalo discloses a winged catheter assembly and is directed to a technique for taping the catheter assembly onto the patient. The needle hub does not include finger grips and thus does not direct the grip of the clinician. The push tab of Kvalo is on the catheter adapter (not on a shield). In fact, there is no teaching or suggestion of using a needle shield with the device of Kvalo at all. A plug 20 is provided at the proximal end of the needle hub. This plug is depicted as a vented plug, with a flat proximal end (not convex). In use, as blood enters the needle during insertion, air is forced through the plug, out the proximal end of the plug. The blood passes to a transparent blood detection chamber (also known as a flash chamber), confirming to the clinician that the vein has been successfully accessed. As such, it is not desirable to use the proximal end of the plug as a thumb pad because that might interfere with the air flow through the plug (and thus the blood confirmation to the clinician).

Purdy teaches a catheter introducer assembly including a needle tip shield and a push tab, but no wings are depicted. There is no teaching or suggestion to combine the wings of Kvalo with the introducer assembly of Purdy to achieve the claimed invention. Even if Kvalo and Purdy were combined (and there is no teaching that such a combination could be made), there is no teaching in either reference of a convex thumb pad or oval finger grips. The Examiner has stated that, at least with respect to the oval finger grips, it would have been a mere obvious matter of design choice. Applicant's Attorney respectfully disagrees and notes that there are no facts of record that support the Examiner's position. The

design of claim 1 provides the caregiver with an opportunity to select from various insertion techniques. This flexibility is emphasized by various aspect of the claimed structure, including the oval finger grips and the convex thumb pad. These structures are simply absent from the cited references. In fact, it is somewhat counterintuitive that the inclusion of specific structure to position the clinician's fingers, as set forth in claim 1, would result in technique flexibility. Ultimately, there is no teaching or suggestion to combine the cited references, let alone to modify the cited references to achieve the claimed structure. Indeed, one might be dissuaded from forming a thumb pad at the proximal end of the Kvalo and Purdy devices for fear of interfering with the operation of the flashback chamber. Consequently, claim 1 is believed patentable over Purdy and Kvalo, either alone or in combination.

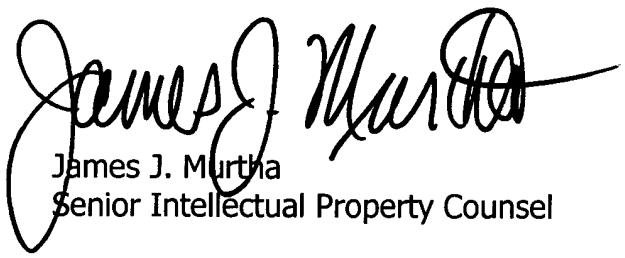
Independent claim 8 as also directed to a multi-grip needle and catheter assembly. A needle hub is provided with finger grips and a thumb pad. A needle shield is slidably disposed about the needle. A push tab is disposed proximal of the needle hub. Claim 9 includes, inter alia, that the distal edge of the wing has a smooth, continuous convex shape along its entire length. Claim 10 requires a side port is attached to the catheter adapted and formed integral with the wing. As discussed above, Kvalo does not disclose a shield for the needle and Purdy does not include wings. There is not a teaching or suggestion to combine these references to achieve the claimed invention. Further, Edwards, which does disclose a side port, does not teach or suggest that such a side port could be combined with selected additional structures from Kvalo and/or Peterson to achieve the claimed invention. Consequently, claims 8-10 are believed patentable.

Independent claim 11 requires, inter alia, at least one wing attached to the catheter adapter. The wing has a smooth convex shape along its distal edge. This smooth shape permits the clinician precise control during insertion. Specifically, the clinician can roll the distal edge along his finger, thereby rotating the needle and catheter assembly to a desire orientation. While Kvalo shows a

proximal edge that is convex, it is not a smooth convex shape and would not provide this control benefit. Neither Purdy nor Edwards disclose a convex wing at all, let alone the smooth convex shape of claim 11. Consequently, claim 11, and claims 12-17 which depend therefrom, are believed patentable over the cited art.

The application is now believed to be in condition for allowance and prompt and favorable action is respectfully requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned.

Respectfully submitted,



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